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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,442	02/20/2004	W. Robert Addington	70538.UT	7778

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EXAMINER

HOEKSTRA, JEFFREY GERBEN

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 12/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/783,442	Applicant(s) ADDINGTON ET AL.	
	Examiner Jeffrey G. Hoekstra	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9, 10 and 14-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9, 10 and 14-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice of Amendment

1. In response to the amendment filed on 09/25/2006, amended claim(s) 15, and canceled claim(s) 1-8, 11-13, and 17-23, is/are acknowledged. The following new and reiterated grounds of rejection are set forth:

Claim Objections

2. Claim 15 is objected to because of the following informalities: the term "substantially" in claim(s) 15 is a relative term that appears to render the claim(s) indefinite. The term "substantially" is not defined by the claim(s), the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. The composition of the cough-inducing substance is unclear. Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Art Unit: 3736

4. Claims 9-10 and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Hill et al (US 6,735,471). Hill et al discloses an apparatus as broadly as *structurally* claimed, comprising:

- a nebulizer capable of being actuated to atomize a cough-inducing substance contained therein (column 4 lines 5-23 and the drug delivery means positively recited in column 5 lines 22-26);
- an electrical switch (250) associated with said nebulizer (column 16 lines 10-30);
- an EMG machine (230) having one or more EMG sensing electrodes (270); and
- a connection comprising at least one wire between said switch and said EMG machine (the wires as best seen in Figure 1).

5. Claims 9 and 16 contain product-by-process subject matter, the examiner notes the determination of patentability in a product-by-process claim is based on the product itself, even though the claim may be limited and defined by the process. That is, the product in such a claim is unpatentable if it is the same as or obvious from the product of the prior art, even if the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 697, 227 USPQ 964, 966 (Fed. Cir. 1985). A product-by-process limitation adds no patentable distinction to the claim, and is unpatentable if the claimed product is the same as a product of the prior art.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 3736

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hill et al in view of Chen et al (US 2002/0032171 A1). Hill et al discloses the claimed pulmonary stimulation and measurement apparatus, including delivering a drug composition into a patient, except for explicitly disclosing a cough-inducing substance containing one or more salts of tartaric acid including a composition made with up to 20% tartaric acid. Chen et al discloses the use of atomized tartaric acids and salts in therapeutic pharmacological agents (paragraphs 24, 104-106, and table 19). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Hill et al, with Chen et al for the purpose of increasing the efficacy of a desired drug-induced response via administered pharmacological agents to increase patient response during advanced medical procedures.

Response to Arguments

9. Applicant's arguments, see page 6 line 9 – page 7 line 17, filed 09/25/2006, with respect to the double patenting rejections of claims 9 and 15 have been fully considered and are persuasive. The double patenting rejections of claims 9 and 15 have been withdrawn.

10. Applicant's arguments, see page 7 line 18 – page 8 line 15, filed 09/25/2006, with respect to the 101 and 112 rejections of claim 9 have been fully considered and are persuasive. The 101 and 112 rejections of claim 9 have been withdrawn.

11. Applicant's arguments, see page 8 line 16 – page 10 line 5, filed 09/25/2006 have been fully considered but they are not persuasive. Applicant argues Hill et al fails to anticipate the as claimed instant invention because (a) Hill et al does not disclose an EMG machine, (b) Hill et al does not teach or suggest "an electrical switch associated with said nebulizer and responsive to actuation of said nebulizer", (c) Hill et al does not teach or suggest an EMG machine having one or more sensing electrodes connectable to the patient for sensing muscular electrical activity; and a connection between said switch and said EMG machine to thereby activate the EMG machine responsive to said switch". Applicant also argues (d) a prima facie case of obviousness is not established for the rejection of claims 14 and 15 as unpatentable over Hill et al in view of Chen et al because there exists "no argument why it would have been obvious to utilize a salt of tartaric acid or tartaric acid itself in view of a teaching of 'deactivated tartaric acid esters of mono-and diglycerides". The examiner disagrees and maintains the

Art Unit: 3736

anticipatory 102(b) rejection of claims 9-10 and 16 and the 103 rejections of claims 14-15.

12. Regarding the argument that Hill et al does not disclose an EMG machine, the Examiner notes Hill et al positively recites physiological sensing and monitoring electrodes (270) and an associated machine (230) capable of measuring an EMG signal as broadly as structurally claimed.

13. In response to applicant's argument that (b) and (c), a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Furthermore, the examiner notes the determination of patentability in a product-by-process claim is based on the product itself, even though the claim may be limited and defined by the process. That is, the product in such a claim is unpatentable if it is the same as or obvious from the product of the prior art, even if the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 697, 227 USPQ 964, 966 (Fed. Cir. 1985). A product-by-process limitation adds no patentable distinction to the claim, and is unpatentable if the claimed product is the same as a product of the prior art.

14. In response to applicant's argument (d) that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the

Art Unit: 3736

references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, both Hill et al and Chen et al disclose apparatus for introducing medication into a patient, specifically Chen et al teaches alveoli wetting ionic surfactants including atomized compounds of tartaric acids and salts in therapeutic pharmacological agents (paragraphs 24, 104-106, and table 19).

Conclusion

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is

Art Unit: 3736

(571)272-7232. The examiner can normally be reached on Monday through Friday, 8:00 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JH

JH



MAX F. HINDENBURG

SENIOR PATENT EXAMINER

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